



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,353	11/13/2001	Richard N. Ellson	7610-0002.20	1207
23980	7590	03/15/2004	EXAMINER	
REED & EBERLE LLP 800 MENLO AVENUE, SUITE 210 MENLO PARK, CA 94025			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER

1634

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,353

Applicant(s)

ELLSON ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-44, 91, 93-103 and 107-109 is/are pending in the application.
- 4a) Of the above claim(s) 109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 11-44 91 93-103 107-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1634

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 December 2003 has been entered.

Status of the Claims

2. This action is in response to papers filed 22 December 2003 in which claims 1, 5-8, 13-17, 21-22, 25, 29-30, 33-36, 41, 44, 91, 94 and 96 were amended and claims 107-108 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 22 September 2003, not reiterated below are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the instant rejections. New grounds for rejection are discussed.

Claim 109 is withdrawn from prosecution.

Claims 1-9, 11-44, 91, 93-103, 107-108 are under prosecution.

Art Unit: 1634

Election/Restrictions

3. Newly submitted claim 109 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 109 and the originally claimed invention are related as product and method for using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the originally claimed product can be used in a variety of processes e.g. for making replica substrates and for synthesis of probe-encoded molecules which do not require target moiety, target moiety contact and/or reading and detecting as required by newly claimed method of Claim 109.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 109 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1634

5. Claims 1-9, 11-44, 91, 93-103, 107-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "a source of the target moiety" is added to the newly amended independent claim 1 from which all pending claims depend. However, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

35 U.S.C. 112: second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-9, 11-44, 91, 93-103, 107-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-9, 11-44, 91, 93-103, 107-108 are indefinite in Claim 1 for the recitation "detectable/readable" because it is unclear what is intended by the "/" between "detectable" and "readable". Hence, it is unclear whether the recitation limits the claim to detectable **and** readable or detectable **or** readable.

Art Unit: 1634

b. Claims 13-17, 21-22 and 107 are each indefinite for the recitation "detectable/readable" for the reasons stated directly above.

c. Claims 11 and 12 are indefinite in Claim 11 for the recitation "no less than about".

d. Claims 33-36 are each indefinite for the recitation "at least about".

It is vague and indefinite what is meant by the phrases "no less than about 1" and "at least about 5,000 (50,000; 200,000; or 1,000,000) probe moieties". The phrases "at least" and "no less than" typically indicates a minimum point. The phrases "at least" and "no less than" however, are contraverted by the term "about" which implies that values above and below those recited are permitted. Further, the extent of variance permitted by "about" is unclear in this context. Therefore, it is also unclear if "about 50,000" simply includes 45,000 or if it also includes 20,000 as well. In Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, "The district court held claims 4 and 6 of the patent invalid because their specific activity limitation of "at least about 160,000" was indefinite". After review, the CAFC states "We therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the specification.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-9, 11-44, 91, 93-103, 107-108 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a substrate comprising probe moieties and machine-readable information wherein e.g. the information is represented by a data signal, contains the identity of a customer, contains shipping and/or billing information, contains identify of at least one probe moiety, information relating to a process, information relating to experimental

Art Unit: 1634

conditions, information relating to experimental results, information represented by no less than about 1 megabyte. The claimed information merely describes the information contained on the substrate but is not functionally interrelated with the substrate i.e. the information does not cause or perform any functional change with or on the substrate. Therefore, the claimed information is non-functional descriptive material.

The courts have provided guidance regarding non-functional descriptive material (see MPEP § 2106 IV).

Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759: the mere manipulation of abstract ideas, Schrader, 22 F.3d at 292-93, 30 USPQ2d at 1457-58, are not patentable. Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. In re Sarkar, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978) Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process,

Art Unit: 1634

machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 1, 5-9, 11-17, 21-22, 30-32, 37-43, 91, 96-103, 107 and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998).

The claims are broadly drawn to a device comprising a substrate and machine readable information. The claims are replete with broad terms and phrases e.g. “represented by”, “relating to”, “associated with”, “capable of”, “with respect to”. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the broad claim language as detailed below.

Art Unit: 1634

Regarding Claim 1, Virtanen discloses a device comprising a substrate having a plurality of probe moieties attached to a surface thereof and containing machine readable information relating to the moieties wherein the information is physically associated with the substrate (Abstract; Column 5, lines 14-27 and Column 42, line 67-Column 43, line 58) and further comprising a source of the target moiety. The claimed "source" is broadly consist with to encompass anyone of the sources disclosed by Virtanen e.g. patient (Column 23, lines 8-13); sample inlet port (Column 53, lines 55-63 and Fig. 20); sample delivery devices (Column 60, lines 41-46); and pipetting robot (Column 63, lines 12-46).

Regarding Claim 5, Virtanen discloses the device wherein the information contains the identity of at least one moiety attached to the surface (Column 14, lines 35-67 and Column 45, lines 59-67).

Regarding Claim 6-8, Virtanen discloses the device wherein the information is analyte-specific information (Column 15, lines 1-22) and analyte-specific information "relates" to analyte attachment processes, analyte experimental conditions and analyte experimental results. As such, Virtanen discloses the device as claimed.

Regarding Claim 9, Virtanen discloses the device wherein the information is digital (Column 3, lines 13-27).

Regarding Claims 11-12, Virtanen discloses the device wherein the information is on a CD or DVD which represents about 1 to 650 megabytes (Column 4, lines 13-35. Therefore, the information on the DC or DVD is represented by about 1 to 650 megabytes as claimed.

Regarding Claim 13, Virtanen discloses the device wherein the information is in a format that is optically readable (Column 5, lines 23-27).

Regarding Claim 14, Virtanen discloses the device wherein the information is in a format that is readable by a fluorescence reader (Column 38, line 65-Column 40, line 58).

Regarding Claim 15, Virtanen discloses the device wherein the information is in a format that is readable by a phosphoimager (Column 38, line 65-Column 40, line 58).

Art Unit: 1634

Regarding Claim 16, Virtanen discloses the device wherein the information is in a format that is readable by a compact disc reader (Column 5, lines 13-22).

Regarding Claim 17, Virtanen discloses the device wherein the information is in a format that is readable by a DVD (Column 5, lines 13-22).

Regarding Claim 21, Virtanen discloses the device wherein the information is magnetically readable (Column 38, line 65-Column 39, line 60 and Column 40, lines 17-58).

Regarding Claim 22, Virtanen discloses the device wherein the information is electronically readable (Column 38, line 65-Column 39, line 60 and Column 40, lines 17-58).

Regarding Claim 30, Virtanen discloses the device wherein the moieties comprise an array of biomolecules (Claim 8 and 9).

Regarding Claim 31, Virtanen discloses the device wherein the biomolecules are nucleotidic or peptidic (Claim 8 and 9).

Regarding Claim 32, Virtanen discloses the device wherein the biomolecules are oligomeric or polymeric (Claim 8 and 9).

Regarding Claim 37, Virtanen discloses the device wherein the substrate comprises a disk (Column 5, lines 14-27).

Regarding Claim 38, Virtanen discloses the device wherein the substrate comprises a tape i.e. strip (Column 7, lines 51-65).

Regarding Claim 39, Virtanen discloses the device wherein the substrate comprises a well plate (Column 7, lines 51-65).

Regarding Claim 40, Virtanen discloses the device wherein the substrate comprises a slide (Column 7, lines 51-65).

Regarding Claim 41, Virtanen discloses the device wherein the substrate comprises a plurality of surfaces arranged in a three-dimensional structure to which moieties are attached i.e. well plate (Column 7, lines 51-65).

Art Unit: 1634

Regarding Claim 42, Virtanen discloses the device wherein the substrate comprises an additional magnetic medium i.e. labeled moieties (Column 40, line 59-Column 41, line 7).

Regarding Claim 43, Virtanen discloses the device wherein the substrate comprises an additional optical medium i.e. labeled moieties (Column 40, line 59-Column 41, line 7).

Regarding Claim 91, Virtanen discloses the device wherein the information is contained in a discrete region of the substrate surface having the plurality of moieties (Column 15, lines 12-15).

Regarding Claim 96, Virtanen discloses the device wherein the information and the attached moieties exhibit positional correspondence (Column 9, lines 55-59 and Fig. 11C).

Regarding Claim 97, Virtanen discloses the device wherein the substrate has a radial mass distribution that is symmetric about an axis perpendicular to the plane of the substrate (Column 9, lines 44-65 and Fig. 11).

Regarding Claim 98, Virtanen discloses the device wherein the substrate is in the form of a disk (Column 7, lines 51-65).

Regarding Claim 99, Virtanen discloses the device wherein the information is contained in a computer microchip i.e. silicon chip (Column 7, lines 56-59).

Regarding Claim 100, Virtanen discloses the device wherein the information is stored in a medium capable of emitting radiation (Column 13, line 66-Column 14, line 47).

Regarding Claim 101, Virtanen discloses the device wherein the radiation is electromagnetic radiation (Column 13, line 66-Column 14, line 47 and Column 40, line 60-Column 41, line 28).

Regarding Claim 102, Virtanen discloses the device wherein the radiation is a fluorescent medium (Column 13, line 66-Column 14, line 47 and Column 40, line 60-Column 41, line 28).

Art Unit: 1634

Regarding Claim 103, Virtanen disclose the information is on a DC or DVD (Column 5, lines 17-22) and therefore teach the information is "represented" by no less than 1 kilobyte as claimed.

Regarding Claim 107, Virtanen disclose the device wherein the response and data signals are in radioactively detectable/readable form (Column 40, line 59-Column 41, line 7, especially, line 5).

Regarding Claim 108, Virtanen disclose a machine comprising the device of Claim 1 further comprising a means for applying target e.g. pipetting robot (Fig. 44) and means for reading information and detecting response signal (Column 7, lines 10-59).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 2-4, 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998) in view of Hammock et al (U.S. Patent No. 6,395,562, filed 4 September 1998).

Regarding Claims 2-4, Virtanen discloses a device comprising a substrate having a plurality of probe moieties attached to a surface thereof and containing machine readable

Art Unit: 1634

information relating to the moieties wherein the information is physically associated with the substrate (Abstract; Column 5, lines 14-27 and Column 42, line 67-Column 43, line 58) and further comprising a source of the target moiety. The claimed "source" is broadly consist with to encompass anyone of the sources disclosed by Virtanen e.g. patient (Column 23, lines 8-13); sample inlet port (Column 53, lines 55-63 and Fig. 20); sample delivery devices (Column 60, lines 41-46); and pipetting robot (Column 63, lines 12-46).

Furthermore, Virtanen teach the information encompasses various types of information relating to the attached moieties including patient information, diagnostic information, assay information and interpretive information (Column 15, lines 1-22) which clearly suggests that the information includes customer information, secure information and shipping and/or billing information. Furthermore, Hammock et al who teach a similar device comprising a substrate and readable information also teach that the information includes various types of information relating to the attached moieties (Column 2, lines 23-25, Column 3, lines 15-18 and 44-64). This too suggests that the information relating to the moieties includes customer information, secure information and shipping and/or billing information.

However, the courts have stated that non-functional descriptive material does not distinguish a claimed invention over the prior art.

Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). Common situations involving nonfunctional descriptive material are: a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium, See MPEP 2106. A combination including printed matter and structure wherein the features of structure are old and the relationship of the printed matter to the structure is old, so that any novelty is in the meaning or significance of the words used in the printed matter, is not patentable as a manufacture in the sense of 35 U.S.C. 101". *Boyle et al. v. Ladd*, 138 USPQ 289 (D.C.D.C. 1963); *Ex parte Gwinn, Jr.*, 112 USPQ 439 (1955); *Conover v. Coe*, 69 App. D.C.

Art Unit: 1634

144, 99 F.2d 377, 38 USPQ 309 (1938), and In re Russell, 18 CCPA 1184, 48 F.2d 668, 9 USPQ 181 (1931).

Therefore, because the courts have stated that nonfunctional descriptive material encoded on a medium does not distinguish an invention from the prior art and because the prior art teaches the claimed structural components and suggests the instantly claimed customer identity information, secured information and shipping and/or billing information. The instantly claimed devices of Claims 2-4 are obvious in view of the teachings of Virtanen and Hammock et al and the guidance provided by the courts.

Regarding Claims 33-36, Virtanen utilizes the surface for spatially resolved assays (Column 14, line 53-Column 15, line 22) but is silent regarding the density of moieties on the surface. However, Hammock et al teaches the similar device wherein the surface comprises moiety arrays of $100\mu\text{ m}^2$ which encompasses the claimed about 1,000,000 moieties/ cm^2 (Column 5, lines 60-65 and Claim 7) and wherein the dimension is particularly desirable for spatially resolved assays. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the moiety dimension of Hammock et al to the surface of Virtanen and to attach about 1,000,000 moieties per square centimeter thereby providing for spatially resolved assays as taught by Hammock et al (Column 5, lines 60-65) and as desired by Virtanen (Column 14, line 53-Column 15, line 22)

14. Claims 1, 2-9, 11-13, 18-27, 31-32, 37, 39-40, 42-44, 91, 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al. (U.S. Patent No. 6,284,459 B1, filed 5 September 1996) in view of Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998).

Regarding Claim 1, Nova et al. disclose a device comprising a substrate having a plurality of molecule moieties attached to a surface thereof and machine-readable information relating to the molecular moieties wherein the information is contained in a discrete region of the substrate that is noncoplanar with respect to the surface having the plurality of moieties attached thereto (Column 42, lines 46-67 and Fig. 26-27) wherein the machine-readable information contains information relating to the molecule identity, their process of preparation, their batch number, category, physical properties and chemical properties (Column 8, lines 42-47) wherein the substrate comprises a disk i.e. silicon chip (Column 19, line 41-Column 20, line 1). Nova et al are silent regarding a source of the target. However, Virtanen et al teach the similar device comprising the claimed source e.g. sample inlet port (Column 53, lines 55-63 and Fig. 20); sample delivery devices (Column 60, lines 41-46); and pipetting robot (Column 63, lines 12-46).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the target source of Virtanen to the device of Nova et al for the obvious benefits of providing ready access for the target to the substrate as illustrated by Virtanen (Fig. 20 and 44).

Regarding Claims 2-4, Nova et al. disclose the device comprising machine-readable information i.e. OMD (Column 19, lines 31-40 and Column 42, lines 46-67). Virtanen teach a similar device comprising a disk and machine readable information wherein the information encompasses various types of information relating to the attached moieties including patient information, diagnostic information, assay information and interpretive information (Column 15, lines 1-22) which clearly suggests that the information includes customer information, secure information and shipping and/or billing information.

However, the courts have stated that non-functional descriptive material does not distinguish a claimed invention over the prior art. Because the courts have stated that nonfunctional descriptive material encoded on a medium does not distinguish an invention

Art Unit: 1634

from the prior art and because the prior art teaches the claimed structural components and suggests the instantly claimed customer identity information, secured information and shipping and/or billing information. The instantly claimed devices of Claims 2-4 are obvious in view of the teachings of Nova et al and Virtanen.

Regarding Claim 5, Nova et al. disclose the device wherein the machine-readable information comprises the identify of at least one of the moieties attached to the surface (Column 8, lines 42-47).

Regarding Claim 6, Nova et al. disclose the device wherein the machine readable information comprises information relating to a process by which the moieties are attached i.e. process of preparation (Column 8, lines 42-47).

Regarding Claim 7, Nova et al. disclose the device wherein the machine-readable information comprises information relating to experimental conditions (Column 73, lines 40-54).

Regarding Claim 8, Nova et al. disclose the device wherein the machine-readable information comprises information relating to experimental results (Column 73, lines 40-54).

Regarding Claim 9, Nova et al. disclose the device wherein the machine-readable information is digital (Column 73, lines 45-50).

Regarding Claims 11-12, Nova et al are silent regarding the substrate containing no less than 1 megabyte (Claim 11) and about 1 to 650 megabytes (Claim 12) of machine-readable information. However, machine readable disk substrates comprising 1 to 650 megabytes of data were well known in the art at the time the claimed invention was made as taught by Virtanen (Column 4, lines 13-35) who teach that the that disk device provides for high density information and analyte detection utilizing disk readers known in the art (Column 5, lines 14-27 and Fig. 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the megabyte of data taught by Virtanen to the disk of

Art Unit: 1634

Nova et al for the obvious benefits of providing a large amount of data readable utilizing readily available disk readers as taught by Virtanen (Column 5, lines 14-27).

Regarding Claim 13, Nova et al. disclose the device wherein the machine-readable information is optically readable (Column 9, lines 3-13).

Regarding Claim 18, Nova et al. disclose the device further comprising additional information in a barcode format (Column 39, lines 39-56).

Regarding Claim 19, Nova et al. disclose the device wherein the bar code reader is one-dimensional bar code reader (Column 41, lines 5-13 and 29-44).

Regarding Claim 20, Nova et al. disclose the device wherein the bar code reader is two-dimensional bar code reader (Column 41, lines 5-13 and 29-44).

Regarding Claim 21, Nova et al. disclose the device wherein the machine-readable information is magnetically readable (Column 41, lines 45-47).

Regarding Claim 22, Nova et al. disclose the device wherein the machine-readable information is electrically readable (Column 73, lines 45-50).

Regarding Claim 23, Nova et al. disclose the device further comprising human readable information i.e. orientation indicators (Column 43, lines 20-29).

Regarding Claim 24, Nova et al. disclose the device wherein the attached molecular moieties are protected i.e. screen or mesh (Column 42, lines 46-49 and 61-64).

Regarding Claim 25, Nova et al. disclose the device further comprising a protective layer over the molecular moieties i.e. screen or mesh (Column 42, lines 46-49 and 61-64).

Regarding Claim 26, Nova et al. disclose the protective layer is removable i.e. screen or mesh (Column 42, lines 46-49 and 61-64).

Regarding Claims 27, Nova et al. disclose the device further comprising a protective layer over the molecular moieties wherein the protective layer is composed of a material that allows only selected matter to be transmitted there through i.e. screen or mesh (Column 42, lines 46-49 and 61-64). The functional language "allows only selected matter to be transmitted

Art Unit: 1634

there through” does not further limit the structural components of the device. Therefore, Nova et al. disclose the device as claimed.

Regarding Claim 30, Nova et al. disclose the device wherein the moieties comprise an array of biomolecules (Column 98, lines 30-60).

Regarding Claim 31, Nova et al. disclose the device wherein the biomolecules are nucleotidic (Column 98, lines 30-60).

Regarding Claim 32, Nova et al. disclose the device wherein the biomolecules are oligomeric (Column 98, lines 30-60).

Regarding Claim 37, Nova et al. disclose the device wherein the substrate comprises a disk i.e. silicon chip (Column 19, line 41-Column 20, line 1).

Regarding Claim 39, Nova et al. disclose the device wherein the substrate comprises a well plate (Column 19, line 41-Column 20, line 1).

Regarding Claim 40, Nova et al. disclose the device wherein the substrate comprises a glass slide (Column 19, line 41-Column 20, line 1).

Regarding Claim 42, Nova et al. disclose the device wherein the substrate comprises a magnetic medium (Column 57, lines 14-27).

Regarding Claim 43, Nova et al. disclose the device wherein the substrate comprises an optical medium (Column 57, lines 14-27).

Regarding Claim 44, Nova et al. disclose the device wherein the surface having moieties attached thereto opposes a surface on which the information is located (Column 42, lines 42-45 and Fig. 25).

Regarding Claim 91, Nova et al. disclose the device wherein the information is in a discrete region from the surface having the moieties (Column 42, lines 42-45).

Regarding Claim 93, Nova et al. disclose the device wherein the machine readable information is located on a surface of the substrate that is noncoplanar with respect to the surface adapted for attachment to a plurality of moieties (Column 42, lines 42-45).

Art Unit: 1634

Regarding Claim 94, Nova et al. disclose the device wherein the machine readable information is located on a surface of the substrate that is noncoplanar with respect to the surface adapted for attachment to a plurality of moieties (Column 42, lines 42-45).

Regarding Claim 95, Nova et al. disclose the device wherein the substrate comprises a cartridge (Column 42, lines 33-67 and Fig. 23-27).

Regarding Claim 103, Nova et al. are silent regarding the substrate containing no less than 1 kilobyte of machine readable information. However, machine readable disk substrates comprising no less 1 kilobyte of data were well known in the art at the time the claimed invention was made as taught by Virtanen (Column 4, lines 13-35) who teach that the disk device provides for high density information and analyte detection utilizing disk readers known in the art (Column 5, lines 14-27 and Fig. 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the more than one kilobyte of data taught by Virtanen to the disk of Nova et al. for the obvious benefits of providing a large amount of data readable utilizing readily available disk readers as taught by Virtanen (Column 5, lines 14-27).

Conclusion

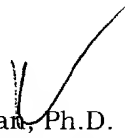
15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 11, 2004